National Standards for Feed Regulatory Programs
A joint project between the U.S. Food and Drug Administration and the Association of American Feed Control Officials

March 11, 2014

Background and Development

Background - Timeline

- Sept. 2009 – FDA released a visioning document for creating an Integrated Food Safety System

- August 2010 – Creation of national standards for animal feed programs was recommendation from PFP 50-State workshop

- October 2010 – AAFCO and FDA discussed entering into partnership to develop feed standards

Background – Timeline (cont.)

- January 2011 – Passage of FSMA, which calls for enhanced partnerships between FDA and State agencies

- January 2011 – Committee was formed to develop the AFRPS

- July 2013 – Publication of 60-day FR Notice

- November 2013 – Publication of 30-day FR Notice

- January 2014 – Clearance of AFRPS

Background – Why Standards?

- AFRPS helps promote uniformity and consistency among animal feed regulatory programs

- AFRPS provides a platform for mutual reliance within the IFSS

- Provides programs with a mechanism for self-assessment and continual improvement against a national standard

Overview of Development Phase

- Organization of the document consists of the standards and accompanying appendices

- All Committee members were provided an opportunity to review and provide comments on all standards and appendices

- Standards: Program Elements, Outcomes, and Required Documentation

- Appendices: Worksheets and examples

Overview of The AFRPS Standards

1. Regulatory Foundation
2. Training
3. Inspection Program
4. Auditing
5. Feed-Related Illness or Death and Emergency Response
6. Enforcement Program
7. Outreach Activities
8. Planning and Resources
9. Assessment and Improvement
10. Laboratory Services
11. Sampling Program

Standard 1: Regulatory Foundation

- Compare state laws and rules to corresponding Federal laws and regulations

- Defined terms: equivalency, equivalency in effect, and not equivalent

- Required process and timeframe for reviewing statutes, regulations, rules

Standard 2: Training

- Basic and advanced coursework

- Field training

- Continuing education
  - Required contact hours (36 hours:36 months)
  - Defined contact hour (60 minutes)
  - Varied options: speak, attend, learn, read, and publish

Standard 2: Training – cont.

- Provision for missing training documents
  - Inspectors with greater than 5 years experience at the date of the initial self assessment
  - Specific subject areas must be identified and evaluated
  - Evaluation of inspector's previous performance and experience required to determine:
    - Required training for subject area is complete
    - Additional training is needed

Standard 3: Inspection Program

- Define and maintain feed facility inventory

- Categorize feed facilities by required risk factors:
  - the type of processing
  - type of feed
  - compliance history of the feed facility

- Required procedures for updating inventory of feed facilities, inspecting, recall audits, complaints

Standard 4: Auditing

- State internal audit

- Field audit component
  - On-site performance evaluation of inspection and sample collection

- Desk audit component
  - Performance review of inspection and sample collection reports

- Criteria for corrective action defined

Standard 5: Feed-related Illness or Death and Emergency Response

- Procedures for evaluating incoming information

- Criteria for determining appropriate response

- Official action plan or ICS for feed-related emergencies

- Emergency contact list

- Communication

Standard 6: Enforcement Program

- Documented enforcement strategies

- Documented process for annual evaluation of enforcement strategies to identify potential improvements and modification

- Six factors for selecting enforcement tool

- Enforcement matrix provides relative conditions to each factor

Standard 7: Outreach Activities

- Outreach plan required

- Content and design of the outreach plan will vary depending on the State program priorities and mission

- Outreach activity events are documented and evaluated

Standard 8: Planning and Resources

- Workplan required that covers:
  - Inspections
  - Sample Collections
  - Designated timeframe
- Evaluate resources needed to implement workplan and routine program activities
- Evaluate resources needed to implement AFRPS

Standard 9: Program Assessment

- Baseline evaluation
  - Fully met
  - Partially met
  - Not met

- Improvement plan

- Three-year review and evaluation

Standard 10: Laboratory Services

- Formal agreement with laboratories managed outside the program that conduct routine analytical services

- Schedule for analyzing samples

- Procedures for handling samples

- Regulatory testing laboratories
  - AAFCO Quality Assurance/Quality Control guidelines
  - Managerial and technical requirements of ISO/IEC 17025
  - Accredited by a recognized body accreditation body

Standard 11: Sampling Program

- Sampling plan
  - Sampling priorities
  - Sampling and analysis schedule
  - Availability/coordination of analytical support

- Sampling procedures
  - Methods for collecting, storing, and transporting samples
  - Instructions for documenting the sample collection

Implementation

"Prep Steps" for Implementation

- Read the AFRPS thoroughly

- Be aware and understand programmatic and documentation requirements

- Develop a plan to complete a self-assessment of your State feed program

Year 1 - Implementation

- Conduct self-assessment

- Complete a self-assessment worksheet for each standard (except Std 9)

- Complete Appendix 9.1: Assessment and Improvement Plan

- Develop improvement plan

Funding

Auditing

Benefits

Benefits of Implementing Standards
A Tool to Assess Feed Programs

- Increases consistency & uniformity among regulatory agencies

- Improves communications, cooperation, and coordination among agencies

- Allows Federal and State agencies to use each other's findings for effective, timely, and efficient regulatory actions

Benefits of Implementing Standards
A Tool to Assess Feed Programs

- Improves staff training

- Helps identify resources needs

- Improves documentation of accomplishments

- Provides a structured mechanism for self-assessment

Recognition of AFRPS Committee Members

FDA Representatives

Paul Bachman (CVM)

Hitelia Castellanos (ORA)

Meagan Davis (CVM)*

Jim Fear (ORA)

Beverly Kent (project manager)

Anita MacMullan (ORA)*

Diane McDaniel (ORA)

Caleb Michaud (ORA)

Jenny Murphy (co-lead)

AAFCO Representatives

Ali Kashani (co-lead)

Bob Geiger (IN)

Ben Jones (TX)

Doug Lueders (MN)

Nancy Thiex (SD)◊

*formerly with FDA

◊ formerly with SD

Collaboration

Questions?

For additional info, please contact:

Jenny Murphy (jenny.murphy@fda.hhs.gov)

Ali Kashani (akashani@agr.wa.gov)